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Evusheld™ receives Health Canada approval for pre-exposure prophylaxis (prevention) of COVID-19 in immune-compromised individuals

PUBLISHED 14 April 2022

Evusheld is the first long-acting antibody (LAAB) combination to receive Health Canada authorization for the prevention of COVID-19

MISSISSAUGA, ON, April 14, 2022 – AstraZeneca's *Evusheld* (tixagevimab co-packaged with cilgavimab), a long-acting antibody combination has received a Notice of Compliance from Health Canada for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (≥12 years of age weighing at least 40kg), who have not had a known recent exposure to an individual infected with SARS-CoV-2 and who are immune-compromised and unlikely to mount an adequate immune response to COVID-19 vaccination **or** for whom COVID-19 vaccination is not recommended. Pre-exposure prophylaxis with *Evusheld* is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.¹

The approval follows AstraZeneca's announcement in February that it had signed an [agreement with the Government of Canada](#) for the supply of *Evusheld*, which is now in Canada. The approval by Health Canada was based on results from the *Evusheld* clinical development program, including data from the [PROVENT](#) Phase III pre-exposure prophylaxis trial which showed a 77% reduction in the risk of developing symptomatic COVID-19 compared to placebo at the primary analysis and an 83% reduction at a six-month median analysis, with protection from the virus lasting at least six months.¹⁻³ *Evusheld* was generally well-tolerated in the trial.¹⁻³

"For people who have weakened immune systems, such as those living with cancer, transplant, dialysis, various genetic immune disorders or autoimmune conditions, or those receiving chemotherapy or certain types of immunosuppressive medications, vaccines alone may not offer sufficient protection against COVID-19," said Dr. Donald Vinh, Infectious Disease specialist and Medical Microbiologist. "These individuals may not consistently generate adequate antibody responses to vaccination against COVID-19, leaving them potentially vulnerable. Long-acting antibodies can complement vaccines and address this vulnerability gap, delivering more reliable protection. These long-acting antibodies are a highly welcomed tool, enabling us to provide another option to at-risk patients."

Approximately 2% of the global population is considered at increased risk of an inadequate response to a COVID-19 vaccine.^{4,5} Additionally, more than 40% of those hospitalized with breakthrough COVID-19 infections after vaccination are immune-compromised.^{6,7} This includes people with blood cancers or other cancers being treated with chemotherapy, and those taking medications after an organ transplant or who are taking immunosuppressive drugs for conditions, including multiple sclerosis and rheumatoid arthritis.⁸⁻¹¹

"For vulnerable populations, such as those who are immune-compromised, *Evusheld* helps to address an unmet need in the ongoing fight against COVID-19," said Kiersten Combs, President of AstraZeneca Canada. "The key to ending the COVID-19 pandemic is protecting as many people as possible against infection, including those who may need an additional layer of protection to prevent COVID-19 than vaccines alone can provide. We welcome today's approval as an important step along this journey."

The recommended dose of *Evusheld* in Canada is 300mg, administered as two separate sequential intramuscular injections of 150mg of tixagevimab and 150mg of cilgavimab. Consideration should be given to increase the dose to 600mg in regions where Omicron BA.1 and Omicron BA.1.1 subvariants are circulating. A patient's healthcare professional will decide which dose will be appropriate to administer.

There is a growing body of evidence from multiple independent in vitro and in vivo (animal model) studies supporting the potential of *Evusheld* to protect against the BA.1, BA.1.1 and BA.2 Omicron SARS-CoV-2 subvariants in circulation around the world.¹²⁻¹⁴ New [data](#) from Washington University School of Medicine demonstrated *Evusheld* retained potent neutralizing activity against the emerging and highly transmissible BA.2 subvariant, which accounted for over 39% of variants of concern in Canada as of March 20th 2022.^{15,16}

Evusheld is the only long-acting antibody combination with positive Phase III data in the prevention and treatment of COVID-19.^{2,17} AstraZeneca is progressing with filings around the globe for potential emergency use authorization or marketing approval of *Evusheld* in both COVID-19 prophylaxis and treatment.

About *Evusheld*

Evusheld, formerly known as AZD7442, is a combination of two long-acting antibodies –

tixagevimab (AZD8895) and cilgavimab (AZD1061) – derived from B-cells donated by convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and [licensed to AstraZeneca in June 2020](#), the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein¹⁸ and were optimized by AstraZeneca with half-life extension and reduction of Fc effector function and complement C1q binding. The half-life extension more than triples the durability of its action compared to conventional antibodies;¹⁹⁻²¹ data from the Phase III PROVENT trial show protection lasting at least six months.^{1,3} The reduced Fc effector function aims to minimize the risk of antibody-dependent enhancement of disease – a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.²²

Evusheld has been granted marketing authorization in the European Union, and conditional marketing authorization in Great Britain and Australia for pre-exposure prophylaxis (prevention) of COVID-19. In the United States, *Evusheld* is authorized for emergency use for pre-exposure prophylaxis of COVID-19. *Evusheld* is also authorized for use and is being supplied in several other countries around the world.

About AstraZeneca Canada

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References

1. *Evusheld* Canadian Product Monograph. Available at: <https://www.astrazeneca.ca/en/our-medicines.html>. [Last accessed: April 2022].
2. AstraZeneca news release. AZD7442 PROVENT Phase III prophylaxis trial met primary endpoint in preventing COVID-19. Available at: <https://www.astrazeneca.com/media-centre/press-releases/2021/azd7442-prophylaxis-trial-met-primary-endpoint.html>. [Last accessed: March 2022].
3. AstraZeneca news release. New analyses of two AZD7442 COVID-19 trials in high-risk populations confirm robust efficacy and long-term prevention. Available at: <https://www.astrazeneca.com/media-centre/press-releases/2021/new->

[analyses-of-two-azd7442-covid-19-phase-iii-trials-in-high-risk-populations-confirm-robust-efficacy-and-long-term-prevention.html](#). [Last accessed: March 2022].

4. Oliver, S. Data and clinical considerations for additional doses in immunocompromised people. ACIP Meeting July 22, 2021. Available at: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-07/07-COVID-Oliver-508.pdf>. [Last accessed: December 2021].

5. Harpaz R, et al. Prevalence of immunosuppression among US adults, 2013. JAMA. 2016 Dec 20;316(23):2547-2548. Available at: <https://doi.org/10.1001/jama.2016.16477>. [Last accessed: November 2021].

6. Tenforde MW, et al. Effectiveness of SARS-CoV-2 mRNA vaccines for preventing COVID-19 hospitalizations in the United States. medRxiv. [Preprint] 2021; Available at: <https://doi.org/10.1101/2021.07.08.21259776>. [Last accessed: November 2021].

7. Brosh-Nissimov T, et al. BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully vaccinated hospitalized COVID-19 patients in Israel. Clin Microbiol Infect. 2021; Available at: [https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X\(21\)00367-0/fulltext](https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00367-0/fulltext). [Last accessed: November 2021].

8. Centers for Disease Control and Prevention. Altered Immunocompetence. General Best Practice Guideline for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices. [Online]. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html>. [Last accessed: December 2021].

9. Boyarsky BJ, et al. Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients. JAMA. 2021; 325 (17):1784-1786.

10. Rabinowich L, et al. Low immunogenicity to SARS-CoV-2 vaccination among liver transplant recipients, Journal of Hepatology (2021). doi: <https://doi.org/10.1016/j.jhep.2021.04.020>.

11. Deepak P, et al. Glucocorticoids and B Cell Depleting Agents Substantially Impair Immunogenicity of mRNA Vaccines to SARS-CoV-2. medRxiv [Preprint]. 2021 Apr 9:2021.04.05.21254656. doi: 10.1101/2021.04.05.21254656. PMID: 33851176; PMCID: PMC8043473.

12. Dejnirattisai W, et al. SARS-CoV-2 Omicron-B.1.1.529 leads to widespread escape from neutralizing antibody responses. Cell. 2022;185(3):467-484.e15.

13. VanBlargan LA, et al. An infectious SARS-CoV-2 B.1.1.529 Omicron virus escapes neutralization by therapeutic monoclonal antibodies. Nature Medicine. 2022; 28:490-495.

14. Case, J et al. Resilience of S309 and AZD7442 monoclonal antibody treatments against infection by SARS-CoV-2 Omicron lineage strains. Available at: <https://www.biorxiv.org/content/10.1101/2022.03.17.484787v1>. [Last accessed March 2022].

15. Government of Canada. COVID-19 daily epidemiology update. Available at: <https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html>. [Last accessed: April 2022].

16. COVID CG. (2022). GISAID. Available at: <https://covidcg.org/?groupKey=lineage@ion=Europe&residueCoordinates=1%2C1274&selectedGene=S&tab=group>. [Last accessed: March 2022].

17. AstraZeneca news release. Evusheld reduced risk of developing severe COVID-19 or death in TACKLE Phase III outpatient treatment trial. Available at: <https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/Evusheld-phiii-trial-positive-in-covid-outpatients.html>. [Last accessed: March 2022].

18. Dong J, et al. Genetic and structural basis for recognition of SARS-CoV-2 spike protein by a two-antibody cocktail. bioRxiv. 2021; doi: 10.1101/2021.01.27.428529.

19. Robbie GJ, et al. A novel investigational Fc-modified humanized monoclonal antibody, motavizumab-YTE, has an extended half-life in healthy adults. Antimicrob Agents Chemother. 2013; 57 (12): 6147-53.

20. Griffin MP, et al. Safety, tolerability, and pharmacokinetics of MEDI8897, the respiratory syncytial virus prefusion F-targeting monoclonal antibody with an extended half-life, in healthy adults. *Antimicrob Agents Chemother.* 2017; 61(3): e01714-16.

21. Domachowske JB, et al. Safety, tolerability and pharmacokinetics of MEDI8897, an extended half-life single-dose respiratory syncytial virus prefusion F-targeting monoclonal antibody administered as a single dose to healthy preterm infants. *Pediatr Infect Dis J.* 2018; 37(9): 886-892.

22. van Erp EA, et al. Fc-mediated antibody effector functions during respiratory syncytial virus infection and disease. *Front Immunol.* 2019; 10: 548.

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